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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,107	08/21/2001	Lars A. Hanson	003300-723	5780

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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 03/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

HC

<b>Office Action Summary</b>	<b>Application No.</b> 09/743,107	<b>Applicant(s)</b> HANSON ET AL.	
	<b>Examiner</b> Chih-Min Kam	<b>Art Unit</b> 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 December 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 54-98 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 54,56-65,67,72,74,75,77-85,87,91-96 and 98 is/are rejected.
- 7) ☒ Claim(s) 55,66,68-71,73,76,86,88-90 and 97 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 54-98 are pending.

Applicants' amendments filed August 18 and December 8, 2004 are acknowledged, and applicants' response has been fully considered. The paper copy and computer readable form of Sequence Listing have been submitted, and CRF has been entered, however, the paper copy filed December 8, 2004 has only 33 pages (contains only 96 sequences instead of 102 sequences, 3 pages are missing). A paper copy of complete Sequence Listing has been faxed to Examiner on February 16, 2005. In the amendment filed August 18, 2004, claims 68-71 have been amended, thus, claims 54-98 are examined.

### **Objection Withdrawn**

2. The previous objection to the Sequence Listing is withdrawn in view of applicants' submission of Substitute Sequence Listing in the amendment filed December 8, 2004 and February 16, 2005.

### **Rejection Withdrawn**

#### ***Claim Rejections - 35 USC § 112***

3. The previous rejection of claims 54-98, under 35 U.S.C.112, first and second paragraphs, is withdrawn in view of applicants' amendment to the claim, applicants' submission of Substitute Sequence Listing, and applicants' response at pages 11-13 in the amendment filed August 18, 2004.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1653

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 61-64 and 67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 61-64 are indefinite because claims 61-64 do not further limit claim 55, which recites the specific amino acid sequence (i.e., SEQ ID NO:70), while claims 61-64 recites the peptide of claim 55 further comprises the peptide of SEQ ID NO:101 or 102, or Thr-Lys. Claims 63 and 64 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

6. Claim 67 is indefinite because the claim recites the peptide comprises SEQ ID NO:68, 69, 71, 75-79 and 84-86 which do not conform the amino acid sequence of SEQ ID NO:99, e.g., SEQ ID NO:68 has Ala instead of Cys at position 1 of SEQ ID NO:99; SEQ ID NO:86 has Glu instead of Asn, ornithine, Ala or Nleucine at position 7 of SEQ ID NO:99.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 54, 56-60, 75, 77-85, 87, and 91-96 are rejected under 35 U.S.C. 102(b) as anticipated by Tomita *et al.* (U.S. Patent 5,304,633, publication date: April 19, 1994).

Art Unit: 1653

Tomita *et al.* teach an antimicrobial peptide which has a sequence of Ala-Thr-Lys-Cys-Phe-Gln-Trp-Gln-Arg-Asn-Met-Arg-Lys-Val-Arg-Gly-Pro-Pro-Val-Ser-Cys-Ile-Lys-Arg-Asp (SEQ ID NO:10 in the patent), where the two cysteines at positions 4 and 21 form disulfide bond (column 12, lines 1-24; Experiment 8; claim 60), this sequence comprises SEQ ID NO:99 (X<sub>1</sub> is Gln, X<sub>2</sub> is Trp, X<sub>3</sub> is Gln, X<sub>4</sub> is Arg, X<sub>5</sub> is Asn, X<sub>6</sub> is Met, and X<sub>7</sub> is Arg) and a peptide having Thr-Lys at the amino terminus and Gly-Pro-Pro-Val-Ser-Cys-Ile-Lys-Arg at the carboxy terminus, and it is not SEQ ID NO:38 (claims 54, 56, 57, 58, 59). The reference also teaches the antimicrobial peptide can be formulated and administered to humans or animals and used in food product such as chewing gum or in medicinal products such as eye medications or athlete's foot medications (column 6, line 45-column 7, line 8; Examples 8-15; claims 75, 77-85, 87, 91-96). The term "for treatment or prevention of infections and inflammations", "for treatment or prevention of a urinary tract infection" or "for treatment or prevention of colitis" cited in the claim is an intended use which does not give weight in a product claim.

8. Claims 54, 56-59, 65, 72, 74, 75, 77-85 and 98 are rejected under 35 U.S.C. 102(b) as anticipated by Shimazaki *et al.* (JP-09040578, publication date: February 10, 1997; a computer translated copy is attached; and a formal English translation will be forward to applicant when it is obtained).

Shimazaki *et al.* teach an antiparasitic agent containing a peptide obtained from hydrolysis of lactferrin or a derivative of the peptide, e.g., a peptide has a sequence of Lys-Cys-Phe-Gln-Trp-Gln-Arg-Asn-Met-Arg-Lys-Val-Arg-Gly-Pro-Pro-Val-Ser-Cys-Ile (paragraph [0054], SEQ ID NO:24 in the JP document) or Val-Ser-Gln-Pro-Glu-Ala-Thr-Lys-Cys-Phe-Gln-Trp-Gln-Arg-Asn-Met-Arg-Lys-Val-Arg-Gly-Pro-Pro-Val-Ser-Cys-Ile-Lys-Arg-Asp-Ser-Pro-

Art Unit: 1653

Ile-Gln-Cys-Ile-Gly-Arg-Arg-Arg-Ser-Val-Gln-Trp-Cys-Ala (paragraph [0060]; SEQ ID NO:30 in the JP document), the peptide of SEQ ID NO:30 comprises SEQ ID NO:99 (X<sub>1</sub> is Gln, X<sub>2</sub> is Trp, X<sub>3</sub> is Gln, X<sub>4</sub> is Arg, X<sub>5</sub> is Asn, X<sub>6</sub> is Met, and X<sub>7</sub> is Arg) and a peptide having Thr-Lys at the amino terminus and Gly-Pro-Pro-Val-Ser-Cys-Ile-Lys-Arg at the carboxy terminus, and it is not SEQ ID NO:38 (claims 54, 56, 57, 58, 59), and the derivative is the peptide having the amino group acylated and the carboxyl group amidated (paragraph [0014], claims 65, 72, 74 and 98). The reference also teaches the peptide can be formulated as active agent of antiparasitic agent for oral use or injection (paragraphs [0015], [0018], [0019], claims 75 and 77-85). The term “for treatment or prevention of infections and inflammations”, “for treatment or prevention of a urinary tract infection” or “for treatment or prevention of colitis” cited in the claim is an intended use which does not give weight in a product claim.

### ***Claim Objections***

7. Claims 55, 66, 68-71, 73, 76, 86, 88-90 and 97 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

8. Claims 54, 56-60, 61-65, 67, 72, 74, 75, 77-85, 87, 91-96 and 98 are rejected, and claims 55, 66, 68-71, 73, 76, 86, 88-90 and 97 are objected to.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

Art Unit: 1653

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Patent Examiner

A handwritten signature in black ink, appearing to be 'Chih-Min Kam', with a long horizontal stroke extending to the right.

CMK  
February 23, 2005